

**CLINICAL AND EXPERIMENTAL ASSESSMENT OF THE UP-TO-DATE
TREATMENT OF THE TIBIAL SHAFT FRACTURES**

Doctoral (Ph.D.) thesis

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I. INTRODUCTION, AIMS OF THE STUDY

Introduction

The tibial shaft fractures are 15% of all fractures, which means c.c. 2500 cases per year in Hungary. 90% of these fractures are treated surgically. Injured –who are usually actively working people- will be out of their work for a long time that is why we have to give much attendance in their treatment. During the rehabilitation they spend nearly 2200 days in hospital, which cost more than HUF 450 million per year.

Nowadays the incidence of the tibia fractures is increased, the severity of the fractures is intensified and in spite of new surgical techniques the rate of complications is not dramatically decreased.

In the medical literature there are a lot of publications about the treatment of tibia fractures, operative techniques, complications and rehabilitation. I could find only a few publications about the basic research of the development and prevention of possible complications.

Aims

The treatment of the tibia fractures is one of the most important part of the traumatology, because of weight bearing function, vulnerability and a special soft tissue coverage of the lower extremities. During the treatment of these fractures the most important thing is the “bio-logical” mentality with the conformity of the surgical procedure and the injured biological and biomechanical extremities. During my career I was a witness and active participant in the changes of leg fracture treatment. The aims of my study were the following:

- to present the development of new approaches and surgical techniques in the treatment of the tibia fractures by way of my research and publications.
- clinical examination of the changes in tissue pressure caused by compartment syndrome during the application of the two most common fixation methods for the treatment of tibia fractures, the reamed and unreamed intramedullar nails.

- in basic research: the calorimetric examination of the human muscle tissue in compartment syndrome and Volkmann's ischemic contracture as well as presentation the calorimetric standards of differently damaged muscles.

II. CHANGES IN THE TREATMENT OF TIBIA FRACTURES BY CLINICAL REVIEW

II.1. Aim

To present the changes in the treatment of tibial fractures with retrospective clinical analysis in the following parts:

1. open fractures
2. proximal part fractures
3. distal part fractures

To present the outcomes of two new surgical procedures used for the treatment of leg fractures:

1. Marchetti-Vicenzi nailing
2. Combination of the unreamed intramedullar nail and brace treatment

II.2. The treatment of open tibia fractures with unreamed intramedullar nail

II.2.1 Material and method

For the retrospective clinical examination 12 years (01.01.1995.-31.12.2006.) were chosen. During this period 438 patients were treated because of leg fractures, 36 of them were treated conservatively and 402 surgically.

The fractures and the soft tissue injuries were categorised according to AO. The 98 open fractures were categorised according to Gustillo – Mendoza, 45 of them were grade I, 38 were grade II and 15 were grade III open fractures. For the treatment of the fractures we used unreamed intramedullar nails in 61 cases, 27 of them were grade I, 26 were grade II and 8 were grade III open fractures. We also used unreamed nails for the treatment of 12

closed fractures with serious (Tscherne grade III-IV) soft tissue injuries. Fixateur extern were used in 26 cases of open fractures, 6 of them were grad I open intraarticular, 13 were grad II and 7 were grad III open fractures. We used reamed intramedullar nail only for the treatment of 11 grade I open fractures.

II.2.2. Results

In the cases treated with unreamed nails significantly lower rate of complications were observed during the healing of the fractures and soft tissues than in the cases treated with other methods. Septic complications were developed in 11 (15.3%) cases, 6 (8.3%) of them were deep infections, 4 were healed and in 2 cases a chronic osteomyelitis were developed. Despite these results, in the cases treated with fixateur extern, 16 (66.6%) septic complications were developed (Mann-Whitney non parametric test, $p < 0.01$), 12 (50%) of them were superficial and 4 (16.7%) were deep infections. In the cases treated with nails there were 4 elongated bony consolidations, there were no cases of non-union and malunion degrees bigger than 5. The average time of bony consolidation was 19 weeks. In the cases treated with fixateur extern, however, the average time of bony consolidation was 24 weeks. Elongated bony consolidations were observed in 2 cases, re-fracture was occurred in 1 case, malunions bigger than 5 degrees were observed in 2 cases. The functional outcomes were better (95% excellent) in the cases treated with intramedullar nails. The average hospitalisation time was 12 days in the cases treated with nails and 21 days in the cases treated with fixateur extern (Mann-Whitney non parametric test, $p < 0.05$).

II.3. Unreamed intramedullar nailing of proximal tibia fractures

II.3.1. Material and method

During the examined 12-year- period (01.01.1995.-31.12.2006.) the Marcehetti-Vicenzi nails were used in 42 cases for the treatment of the distal third tibia fractures and for the cases of combined fractures of the tibia diaphysis and condyles. The fractures were categorised according to AO.

There were 19 pcs. of 43A, 14 pcs. of 43B, and 9 pcs. of 43C in the group of diaphyseal fractures and 8 pcs. of B2 and 4 pcs. of B3 type combined fractures. The bony healing was controlled with physical and X-ray examinations 1, 3, 6 and 12 weeks, and 6 and 12 months after the operations.

II.3.2. Results

The average follow up time of the injured was 26 months (9-48 months). During the healing period deep infection did not develop. Two superficial infections were observed in the case of grade II open fracture and in the case of fracture with high energy soft tissue injury. The average healing time was 21 days. We did not have to change the method at all. During the healing of the fractures our results were better than those published in the literature. Malunion bigger than 5 degrees developed in 11 cases and bigger than 10 degrees in 4 cases. Displacement more than 1 cm in the fracture site was observed in 12 cases, rotation bigger than 10 degree were in 7 cases and impression in the joint surface bigger than 2mm were observed in one case. Our functional results were excellent except for one case, where a 5-degree-flexion deficit occurred.

II.4. The treatment of distal tibia fractures with Marchetti-Vicenzi nail

II.4.1. Material and method

The Marchetti-Vicenzi nail is a special type of unreamed nail, which consists of 4 or 5 thin flexible bundle nails 3.5 mm in diameter composed a 10 cm long solid proximal part.

For the treatment of tibial fractures we have been using Marchetti-Vicenzi nails since 1999 in our clinical practice. In the 10-year- period observed (01.01.1997.-31.12.2006.) the nails were chosen in 32 cases for first operations and 3 cases for re-operations. The average age of the injured was 42 years. The operated fractures were categorised according to AO, there were 15 cases type 42 A, B, and C diaphyseal and 10 were type 43A1, 2, and 3 extra- articular fractures. There were 4 type 43 B1 and 3 type 43C1 intra-articular fractures. We used the nail 3 times for the change in method, in

cases of type 43C1 type fractures. Out of the operated fractures there were 5 grade I, 3 grade II and one grade III/A open fractures.

We newly introduced the Marchetti nails for the treatment of low energy intra-articular tibia fractures. With this nail we could fasten the diaphysis to the fractured metaphyseal part stabilised previously with percutaneous screws.

II.4.1. Results

All of the fractures and soft tissue injuries treated with Marchetti nails were healed. The average healing time was 18 weeks in the cases of diaphyseal, 14 weeks in distal and 17 weeks in open fractures. There were no displacements during the healing of intra-articular fractures. Valgus deformities between 5 and 10 degrees were observed in 2 cases. Rotational displacement (10 degree outer rotation) occurred in one patient who suffered from a middle third shaft fracture. There were no non-union and septic complications.

II.5. Adaptation of brace treatment after unreamed intramedullar nailing of tibia fractures

II.5.1. Material and method

Between 01.01.1995 and 31.12. 2006. we operated 224 patients with tibia fractures, brace treatment were used in 144 cases. The fractures were categorised according to AO. The Sarmiento type BTB braces were chosen because the literature presented excellent outcomes with this method. To our knowledge, there have been no publications about the combination of the unreamed intramedullar nail and brace treatment yet. After the adaptation of the brace we permitted gradual weight bearing for the patients until they reached the full weight bearing on the 14th-21st day. The brace wearing was finished by the 12th-16th week. The bony healing was controlled with physical and X-ray examinations 1, 3, 6 and 12 weeks, and 6 and 12 months after the operations.

II.5.2. Results

The results of patients treated with unreamed nail compared to the results treated with the combination of brace and unreamed nail together proved the following:

1. Weight bearing: the average time until full weight bearing was 12 ± 2 weeks in a group treated with unreamed nail, and 4 ± 2 in a group treated with the combination of brace and nail (Mann-Whitney non parametric test, $p < 0.01$). The difference is significant: two months.

2. Healing time: the average healing time of the fracture was 19.6 ± 2.4 weeks in the group treated without brace, and 16.5 ± 2.5 weeks in the group treated with brace and nail (Mann-Whitney non parametric test, $p < 0.01$) The difference is significant too: almost one month.

II.6. Discussion

Since the introduction of the unreamed nails the treatment of tibia fractures has undergone essential changes. During the analysis of our clinical examination the following results were proved:

- The indications of fixateur extern used widely earlier are decreased, while the indications of the unreamed intramedullar nails increased. The unreamed nails became the primary method in the treatment of the following fractures:

- Grade II and III open fractures
- Closed fractures with serious soft tissue injuries
- Unstable diaphyseal fractures
- 2. and 6. seventh fractures

- In Europe, after Italy, we used the Marchetti-Vicenzi nail for the treatment of tibia fractures in the second place. We extended the indications of this new method for the treatment of low energy distal intra-articular fractures.

The most up-to-date conservative method, the dynamic brace, was introduced in the rehabilitation of patients, whose tibia fractures were treated with unreamed intramedullar nails. The combination of the two methods was not published in the literature. Using retrospective clinical examinations I

proved that by the application of the method described the healing period and the rehabilitation of the injured could be shortened.

III. MONITORING OF THE COMPARTMENTAL PRESSURE DURING REAMED AND UNREAMED NAILING OF THE TIBIA

III.1. Aims and hypotheses

The aim of the study was to measure the pressure changes in the intramuscular compartment during the operations and early post-operative periods of the closed tibial shaft fractures treated with reamed and unreamed nails. To compare the results of two different procedures and to investigate if there is any correlation between the different pressure levels and possible complications.

My hypotheses were the following:

- different pressure will develop in the intramuscular compartments during the operations with reamed and unreamed nails of tibia fractures
- pressure parameters monitored during the operations will be higher in the cases of reamed than in unreamed nailings
- the incidence of compartment syndrome will be higher in the cases of reamed intramedullar nailings

III.2. Material and method

24 patients with closed tibia fractures were involved in the study, 12 of them were stabilised with reamed and 12 of them with unreamed intramedullar nails. All patients were prepared for the operations within six hours. The average age of the patients was 43 years.

The compartmental pressure values were measured by KODIAG MBB Class III type pressure monitor in the anterior and deep posterior compartments according to the following protocol:

- before surgery
- during the nails were inserted to the medullar cavity
- 3 and 6 hours after the surgery
- 1 and 3 days after the operations

During the operation the blood pressure of the patients was monitored and an absolutely sensitive rate for the compartment syndrome, the deltaP, was calculated: $\text{deltaP} = \text{diastolic blood pressure} - \text{compartmental pressure}$. Compartment syndrome was proved when the deltaP was lower than 30mmHg or the compartmental pressure was higher than 40mmHg.

Table 1.: Compartmental pressures before, during and 3, 6 hours and 1 day after surgery

Compartmental pressure /Hgmm/ <i>DeltaP /mmHg/:</i>	Before surgery	During surgery	3. hour	6. hour	1. day	3. day
Reamed Anterior	22.1 52.9	34.6 35.4	34.8 33.2	24.2 47.9	10.6 64.4	10.6 69.4
Reamed Posterior	22.9 52.1	30 38.2	31.2 36.7	20.1 54.9	11.6 65.1	9.8 70.2
Unreamed Anterior	21.8 53.2	34.1 35.9	34.2 33.8	22.1 5.9	12.1 62.9	7.2 72.8
Unreamed Posterior	24.6 50.4	35.1 34.9	34.9 33	25.4 46.6	10.9 64.1	8.3 71.7

III.3. Results

There were no significant differences between the pressure and deltaP values measured in the anterior compartment. In the posterior compartment we proved significant differences between the pressure results in the two groups during, and 3 and 6 hours after surgery (Excell Anova variant analysis, $p < 0.05$). In the cases of reamed nailing the pressure values were significantly lower in both moments.

The deltaP values were always over then 30mmHg in the reamed and unreamed groups too. During the examination we could not prove the development of compartment syndrome.

III.4. Discussion

During the investigation I have got the following answers for my questions:

- there are different pressure levels developed in the muscular compartment around the tibia during the usage of two different surgical techniques, the reamed and unreamed nailings.

- the pressure values measured during the surgery are not higher in the cases of reamed nailing, on the contrary in the deep compartment we proved statistically higher pressure in the cases of unreamed nailing than in the cases of reamed nailing.

- during the examination we could not prove the development of compartment syndrome probably because we excluded the fractures with serious soft tissue injuries.

We can draw the conclusion that there is no relationship between the compartmental pressure changes, the chance of the development of compartment syndrome and the insertion technique of the intramedullar nails.

IV. CALORIMETRIC EXAMINATION OF MUSCLE SAMPLES IN COMPARTMENT SYNDROME

IV.1. Aim and hypotheses

The aim of my study was to investigate the muscle samples from compartment syndrome and from Volkmann ischemic contracture with calorimetry and to prove that there is a definitive difference in the structure of the healthy and pathological muscles.

During the research my hypotheses were the following:

- Applying calorimetric examinations we can prove a difference between healthy muscle samples and samples from compartment syndrome and Volkmann's ischemic contracture. The results will follow the degrees of the affected muscle injuries and it could be reproduced.

- There is a correlation between the pressure levels measured in compartment syndrome and the results of calorimetric examination of injured muscle tissues.

IV.2. Material and method

IV.2.1. Sample preparation

The control healthy samples were derived during the operations when one part of the muscle has to be excised. The donors taken into the study were all healthy and under the age of 60. The samples 1x2 cm muscle pieces were taken from different muscles of the lower legs.

The pathologic muscles were derived during operations of different seriousness of compartment syndromes and during operative corrections of Volkmann ischemic contracture. The samples were 1x2 cm muscle pieces too. There were three different groups according to the different stages of the syndrome.

Group I.: acute tibia fracture borderline compartment syndrome, compartmental pressure was between 30 mmHg and 35 mmHg during min. 3 hours.

Group II: acute tibia fracture, definitive compartment syndrome, pressure was over 35 mmHg during min. 3 hours

Group III.: healed tibia fracture, muscle ischemic contractures as the sign of complication of untreated compartment syndrome

We measured 4 samples from the control group, 11 pathologic muscles, 4 from group I, 4 from group II and 3 from chronic cases. In the pathologic group there were three females and five males being in average 48 years (28-57) of age. After removing the muscle pieces they were stored in physiologic saline under 4 degrees Celsius and underwent DSC investigation within 1 our.

IV.2.2. DSC investigation

The pieces of different samples have been prepared and measured within 1 hours of removal. The thermal denaturation of different parts of human samples was monitored by a SETARAM Micro DSC-II calorimeter. All the experiments were performed between 0 and 100 °C. The heating rate was 0.3 K/min. Conventional Hastelloy batch vessels were used during the denaturation experiments with 850µL sample volume (samples plus buffer) in

average. Typical sample wet masses for calorimetric experiments varied in the range of 100 – 200 mg. RPMI-1640 solution was used as a reference sample. The sample and reference vessels were equilibrated with a precision of ± 0.1 mg and there was no need to do any correction from the point of view of heat capacity between the sample and reference vessels. Calorimetric enthalpy was calculated from the area under the heat absorption curve by using two-point setting SETARAM peak integration. The data treatment after ASCII conversion was done by Origin 6.0.

IV.3. Results

The pressure level of the affected muscle compartment is the most important parameter for the clinical outcome of the disease. There is a well proven correlation between the pressure value and the hypoxemic degeneration and structural changes of the muscle tissue. With DSC scans we clearly demonstrated the significant differences between the different stages of compartment syndrome and the calorimetric enthalpy values support this too: in the control $\Delta H_{cal} = 0.52$ J/g, in group I (mild) 0.28 J/g, in group II (severe) 0.24 J/g and in Volkmann's ischemic contracture are 0.74 J/g (Table 2.).

Table 2.: Compartmental pressures and thermal parameters of muscle samples in different stages of compartment syndrome

	Number of samples	Compartmental pressure	T _m (°C)	ΔH _{cal} (J/g)
Healthy	4	<30 mmHg	55.5 ± 0.2 59.9 ± 0.3	-0.52 ± 0.04
I. group mild compartment syndrome	4	30-35 mmHg	58.1 ± 0.2 62.2 ± 0.3	-0.28 ± 0.02
II. group severe Compartment syndrome	4	> 35 mmHg	57.4 ± 0.2 61.5 ± 0.3	-0.24 ± 0.02
Volkmann's ischemic contracture	3		57.8 ± 0.2 61.8 ± 0.3 65.8 ± 0.3	-0.74 ± 0.06

We proved strong significance between the calorimetric enthalpy (ΔH_{cal}) values and the compartmental pressure values: p<0,01 (Student's-T test, SPSS for Windows 9.0). We couldn't prove significance between the melting temperature (T_m) values and the compartmental pressure values.

The thermal parameters and the shape of DSC scans of the healthy and pathologic muscles were absolutely different (figure 1.)

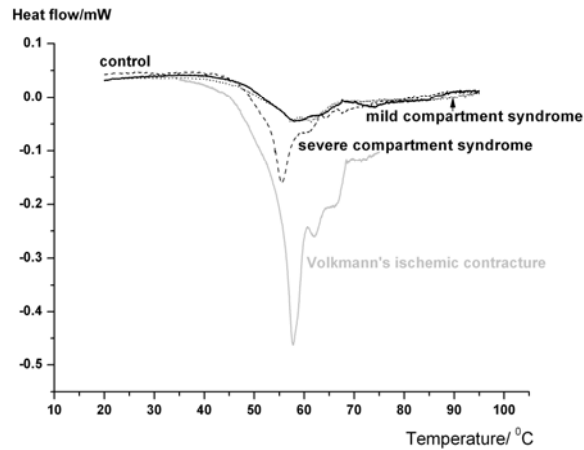


figure 1.: Comparison of different groups DSC scans

Between the samples of group I (mild stage) and the control samples we proved a relevant structural difference with the changes in melting temperature and significant decrease of calorimetric enthalpy values. The modification of the shape of DSC scans could be the sign of severer damage in the actomyosin system.

In group II (severe stage) a further transition temperature change can be observed (T_m s 57.45 and 61.5 °C) with increased actin damage (smaller ΔH_{cal}) as a consequence of marked actin lesions. The modification of the shape of DSC scans proves the complete disorganization of the actomyosin complex caused by hypoxia and tissue necrosis.

In case of Volkmann's ischemic contracture a well definite third thermal compound ($T_m = 65.8$ °C) could be identified which clearly proves a further destroying of the muscle structure with locally more densely packed subunits.

IV.4. Discussion

During the examinations I've got the following answers:

- With differential scanning calorimetry it is possible to detect differences between thermal features of the intact muscles, muscles from compartment syndrome and muscles from ischemic contractures
- There is a strong significance between the pressure value and the thermal parameters of the injured muscles in compartment syndrome.
- Our results have been firmed my hypothesis that with calorimetry we can prove and follow the structural changes of the injured muscle.

The results of the examination may be of clinical relevance in the future.

V. DISCUSSION NEW RESULTS

The aim of my study was to present a clinical and experimental examination of the treatment of tibia fractures and its ischemic complication. I paid special attention on the clinical and basic research of the compartment syndrome and its complications.

V.1. Results of the applications of new methods in the treatment of tibia fractures

- The treatment of the open tibia fractures has essentially changed since the introduction of unreamed intramedullar nails. Before these changes the open tibia fractures were treated with fixateur extern. The unreamed nails became the primary method in the treatment of the Grade ii and III open fractures.

- The unreamed intramedullar nails became sufficient for the treatment of the proximal and distal third tibia fractures, but with higher rate of complications.

- In Hungary we used the Marchetti-Vicenzi nail for the treatment of tibia fractures in first time. Our examinations proved that with this method the tibial shaft and distal part fractures can be treated safely with low rate of complication. We extended the indications of this new technique for the treatment of low energy distal intra-articular fractures.

- In 1997 I prepared the treatment concept of the combination of the dynamic brace and the undreamed intramedullar nail. The combination of the two different techniques was not published in the literature. Using retrospective clinical examinations of 144 patients I proved that by the application of the method described that the advantages of the two treatment form could be attached and the healing period and the rehabilitation of the injured could be shortened.

V.2. Compartmental pressure changes during reamed and unreamed nailing of the tibia

- During the investigation I have proved that there are different pressure levels developed in the muscular compartment around the tibia during the usage of two different surgical techniques, the reamed and unreamed nailing. Contradicting the presuppositions opposite results were gained: the compartmental pressure increased in a greater extent during unreamed than in reamed nailings.

- On the grounds of my research I can declare that for the treatment of closed tibia fracture suffered in monotrauma and low energy injury the first advised fixation method is the reamed intramedullar nail. This technique guarantees high stability, during the application the compartmental pressure and the development of compartment syndrome will not increase in a relevant level.

V.3. Calorimetric examination of the muscle in compartment syndrome

- I proved with differential scanning calorimetry that there is a difference between thermal features of the intact muscles, muscles from compartment syndrome and muscles from ischemic contractures.

- I identified that the DSC scans are absolutely different in both measured groups which prove structural changes in the muscle.

- I also demonstrated that there is a close correlation between the compartmental pressure, the structural damage of muscle tissues and thermo-chemic values measured by calorimetry. Due to their sensitivity and specificity calorimetric examinations can help and support the clinical diagnosis in atypical cases.